REMARKS

Claims 1, 2, 12, 13, 22, 23, 25-30, and 32-72 are pending in the above-referenced application.

Claims 35, 36, 54 and 57 are amended and claims 60-72 are added to further define Applicants' invention.

This is a response to the Office Action dated December 31, 2002 wherein the Examiner rejected claims 50-57 under §102(b) for being anticipated by McLees (U.S. Pat. No. 5,135,504); rejected claims 35-44 under §112, second paragraph, for indefiniteness; objected to the drawings because "a transverse arm and a curved upper segment contiguous with said transverse arm and a proximal wall" are not shown; rejected claims 1, 2, 12, 13, 22, 23, and 25-57 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-109 of U.S. Pat. No. 6,287,278 to Woehr et al. and over claims 1-25 of U.S. Pat. No. 6,117,108 also to Woehr et al.; and have withdrawn claims 3-11, 14-21, 24, and 31. In view of the amendments as indicated above and the remarks that follow, reconsideration and a notice of allowance are respectfully requested.

Preliminarily, because claim 31 has been withdrawn, claim 31 was erroneously included among the list of claims rejected under the judicially created doctrine. Hence, if and when a terminal disclaimer is filed to overcome the rejection, claim 31 will not be included.

§102(b) Rejection of Claims 50-57 by McLees

In rejecting claims 50-57 under §102(b) over McLees, the Examiner contends that "McLees discloses a catheter device (figs. 1-3) and large diameter segment (col. 2, lines 42-59); as to claim 51 and 55, (fig. 2); as to claim 52 and 56, (fig. 3); as to claim 53, (fig. 2); as to claim 54, (a needle crimp disposed proximal the needle tip (fig. 2)); as to claim 57, see above rejection." In view of the amendments as indicated above and the remarks that follow, reconsideration and a notice of allowance are respectfully requested.

As originally introduced in a Preliminary Amendment, independent claim 50 recites A catheter device comprising at least two components that are separable from one another, the first component comprises a catheter hub and a catheter tube fixedly secured thereto; and the second component comprises a needle hub and a needle fixedly secured thereto; wherein the needle comprises a needle tip, a large diameter segment, and a needle shaft, and the catheter tube comprises a catheter passage; and

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wherein the catheter hub and the needle hub further comprise a catheter hub distal end and a catheter hub proximal end, the catheter hub distal end having the catheter tube extending therefrom; a catheter hub opening, the catheter hub opening defining a catheter hub annular space; a needle hub distal end and a needle hub proximal end, the needle hub distal end having the needle extending therefrom; a needle protector clip having a resilient biasing portion; wherein when the needle is in the ready position, which is the position in which the needle projects into the catheter passage and the needle tip extends beyond the catheter tube; the needle protector clip is disposed over the needle and is located within the catheter hub annular space but spaced apart from the needle hub distal end; and wherein when the needle is in a fully retracted position, which is the position in which the needle protector clip moves relative to the needle until the needle is completely withdrawn from the catheter hub annular space, the needle protector clip is activated and attaches to the needle at the needle tip and the large diameter segment; and wherein the resilient biasing portion has a first position and a second position, the first position is characterized by the resilient biasing portion abutting the needle shaft and the second position is characterized by the resilient biasing portion shielding the needle tip and preventing accidental contact with the needle tip.

Preliminarily, Applicants note that for a reference to anticipate a claimed invention, it must adequately meet the terms of the claimed invention interpreted in light of the specification of the application. As set forth in the statute, the single prior art reference must disclose each and every element of the claim under consideration. Moreover, it cannot be rebuilt or reoriented by the utilization of Applicants' teachings in an attempt to create an anticipatory structure.

As recited, Applicants submit that McLees does not anticipate claim 50 by disclosing each and every element and limitations of the claimed catheter device. Among other things, the claimed catheter device recites, in part, a needle protector clip located adjacent to but spaced apart from the needle hub distal end when the needle is in the ready position. In contrast, McLees' discloses a catheter device wherein a guard 6 is positioned adjacent to and abutting the needle hub 4 (See, e.g., FIG. 3). This abutting relationship between the guard 6 and the needle hub 4 is required because McLees also uses a ring 8 to keep the guard 6 in place until the needle tip moves proximal of the guard 6. In essence, the end of the needle hub 4 is utilized to anchor or locate the ring 8 and the guard 6 within the interior space of the catheter hub 3.

Thus, Applicants submit that McLees discloses a device that is substantially different than the catheter device recited in claim 50 and that the McLees device does not anticiapte claim 50 by disclosing each and every element of claim 50 as required by §102(b). Reconsideration and a notice of allowance are respectfully requested.

Because claims 51-53 depend directly from claim 50, they too are allowable over McLees for the same reasons as discussed above for claim 50.

Regarding independent claim 54, it has been amended to recite a catheter device comprising a needle hub having a needle hub proximal end and a needle hub distal end; the needle hub distal end is secured to a needle at the needle's proximal end, the needle has a needle tip, a needle shaft, and a needle crimp disposed proximal of the needle tip; a catheter hub having a catheter hub proximal end and a catheter hub distal end; the catheter hub distal end is secured to a catheter tube at the catheter tube's proximal end; the catheter tube has an opening at a catheter tube distal end and the catheter tube proximal end, and a catheter tube annular space defined between the two openings; wherein the needle and the crimp are disposed within the catheter tube annular space and the needle tip extends beyond the annular space when the needle is in a ready position; and a needle protector for shielding the needle tip and preventing accidental contact with the needle tip when the needle is in a fully retracted position, the needle protector is located adjacent to but spaced apart from the needle hub distal end when the needle is in the ready position, the needle protector comprising an opening for allowing the needle to slide from between the needle ready position and the needle fully retracted position, the needle protector further comprising a protector arm and a protector arm first position and second position, the protector arm first position is a position in which the protector arm is in a flexed state and contacts the needle shaft and the protector arm second position is a position in which the protector arm is in a relaxed state and the needle protector is shielding the needle tip and preventing accidental contact with the needle tip.

Applicants submit that McLees does not anticipate claim 54 by disclosing each and every element of claim 54. Among other things, claim 54 recites, in part, a catheter device wherein the needle protector is located adjacent to but spaced apart from the needle hub distal end, which McLees does not disclose, as discussed above with reference to claim 50. Applicants further submit that such limitations were originally recited. However, to further define the claimed catheter device, claim 54 has been amended as indicated above to more clearly recite the features that are claimed.

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In view of the foregoing, reconsideration and a notice of allowance are respectfully requested.

Because claims 55-56 depend directly from claim 54, Applicants submit that they too are allowable over McLees for the same reasons as claim 54.

Regarding independent claim 57, it has been amended to recite an IV catheter apparatus comprising a tubular catheter having a proximal end and a distal end, a needle having a needle shaft and a tip and wherein the needle is attached to a distal end of a needle hub, said needle being received within said tubular catheter when the needle is in a ready position, a catheter hub attached to the proximal end of said catheter, said catheter hub having a hollow interior and an inner wall, said needle being movable between said ready position in which said tip is outside of said catheter hub and a retracted position in which said tip is within the interior of said catheter hub, a needle guard positioned in the interior of said catheter hub in a spaced apart relationship from the distal end of the needle hub; and wherein the needle guard comprises a resilient portion engaged by said needle shaft when said needle is in its ready position, the needle guard resilient portion is movable within the interior of said catheter hub to a blocking position distal of said needle tip when said needle is in its retracted position in which said needle shaft no longer exerts a force on said resilient portion of said needle guard.

As amended, claim 57 is similar in scope of independent claims 50 and 54. Thus, claim 57 is allowable over McLees for the same reasons as discussed above for claims 50 and 54.

Because claims 58-59 depend directly from claim 57, they should be allowable for the same reasons as claim 57.

§112(2) Rejection of Claims 35-44

In rejecting claims 35-44 under §112, 2nd paragraph, for indefiniteness, the Examiner contends that claim 35 recites the limitation "the underside" without proper antecedent support and in claim 36, the "transverse arm" is not clear to the Examiner. Although claims 37-44 are also rejected under §112, second paragraph, they do not depend from either claim 35 or claim 36, nor did the Examiner explain why they were considered by the Examiner to be indefinite under §112, 2nd paragraph. Hence, Applicants will address the rejection of claims 35 and 36 but are hereby traversing the rejection of claims 37-44 and request for explanation or rescission of the rejection.

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Regarding the term "the underside" in claim 35, it has been amended to recite "a side". The claim should now be definite under §112, 2nd paragraph. Notice thereof is respectfully requested.

Regarding the transverse arm recited in claim 36, Applicants submit that the term is sufficiently defined and exemplary embodiments sufficiently set forth in the various figures, See, e.g., transverse arm 150 in FIGs. 12, 13A, and 13B, and in the specification on page 18, lines 28-31, and arms 122, 124 in FIG. 14. Accordingly, the rejection is traversed.

Objection of the Drawings

In objecting to the drawings under 37 CFR 1.83(a), the Examiner contends that "a transverse arm and a curved upper segment contiguous with said transverse arm and a proximal wall" are not shown in the submitted drawings. To the contrary, Applicants submit that the elements noted are both explained in the specification and shown in the submitted drawings. For example, in the specification on line 28, page 18 to line 12, page 19, the transverse arm 150, the curved upper segment (lip) 154, and the proximal wall 168 are disclosed, which having corresponding elements identified in FIG. 12. The equivalent terms are also used and shown for the spring clip of FIG. 14 (See, e.g., line 20, page 20, to line 34, page 21). Accordingly, rescission of the objection is respectfully requested.

Rejection of Claims 1, 2, 12, 13, 22, 23, and 25-57 under Judicially Created Doctrine of Obviousness-Type Double Patenting

In response to the rejection of claims 1, 2, 12, 13, 22, 23, and 25-57 under judicially created doctrine of obviousness-type double patenting over various claims of U.S. Pat. Nos. 6,287,278 and 6,117,108, Applicants propose that a terminal disclaimer be executed to overcome the rejection. Accordingly, upon receiving a Notice of Allowance, Applicants will hereby submit a terminal disclaimer to address the rejection.

Notwithstanding the foregoing proposal to submit a terminal disclaimer, Applicants note for the record that the assertion that the claims are not patentably distinct from the various claims issued in the '278 patent and the '108 patent is not necessarily the same as stating that the pending claims do not differ in claim scope from the issued claims, which require careful analysis and claim construction to determine.

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In view of the foregoing amendments and remarks, Applicants submit that the application is now in condition for allowance and allowance is respectfully solicited.

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

By _____
Tom H. Dao
Reg. No. 44,641
626/795-9900

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